

REMARKS

This responds to the Office Action of February 12, 2003.

Applicant has made the changes to the specification, abstract and claims as required by the Examiner. In addition, the claims have been modified in accordance with the Examiner's suggestions.

Claim Rejections – 35 U.S.C. § 103

Claim 1 of the application is rejected under § 103(a) as being unpatentable over Clouse 5,211,658 in view of Lam 5,556,413.

The rejection indicates that Clouse discloses a blood vessel wall-defining device except for the ring stents and their respective limitations, and that Lam teaches a coiled stent having controlled expansion that can be locked into an expanded diameter.

Applicant's stent device is structurally and functionally different from the applied references. Clouse discloses a two piece assembly, with a spring coil 48 that winds along the entire length of the expandable inner tubular member 40. The tubular member is telescopically positioned in the structural skeleton 30 and is expanded outwardly into engagement with it. This is a two step process, requiring the handling of two items in a hazardous environment.

In contrast, applicant's product has a structural frame that includes a plurality of longitudinal support rods 20, with a sheath 21 surrounding the rods and connected thereto. This makes the product collapsible to a smaller diameter that is suitable for movement along the length of a blood vessel.

The ring stents 25 are carried with the stent, and the ring stents are expanded, therefore expanding the flexible members 20 and the sheath 21 at the aneurysm.

The sheath 21 is disclosed as enclosing all of or less than all of the length of the elongated flexible members 20. The absence of the sheath intermediate the ends of the device permits the flow of blood to pass about the flexible members 20, particularly when the stent is placed at the intersection of the abdominal aorta artery 11 with other arteries, as illustrated in Fig. 1. Therefore, placement of the ring stents in straddling relationship about the intersecting artery, the elongated flexible members 20 are supported across the intersection, without unduly obstructing the flow of blood between the arteries at the intersection.

In addition, the use of the ring stents 25 enables one ring stent to expand to a larger or to a smaller extent than the others of the ring stents. This allows the overall stent to expand outwardly into an irregular shaped artery, so that the stent is more likely to assume the shape of the artery.

By contrast, Clouse discloses a structural skeleton 30. Clouse states:

As the skeleton 30 is extruded into the abdominal aorta, the skeleton 30 is exposed to body temperature and progressively expands into its high-temperature cylindrical shape as it reaches the body temperature (Fig. 4).
(Column 7, lines 33-36.)

A similar statement is made in claim 1, of the structural frame being expanded to form a generally cylindrical structural skeleton. The tubular member 40 is inserted into the structural skeleton to avoid the collapse of the structural skeleton. The tubular member 40 of Clouse has a single spiral spring coil that supports the rest of the structure. The spaces between the convolutions of the spring appear to provide a rather uniform support along the

length of the tubular member 40 and the structural skeleton 30. Therefore, Clouse is not likely to be able to extend across an intersecting artery without restricting blood flow from one artery to the other.

Claim 1 of the application specifies ring stents that are longitudinally displaced internally of the tubular sheath. This longitudinal displacement provides the ability of having blood flow about the elongated flexible members 20, when the ring stents are not at the intersection of the arteries. Also, the use of ring stents allows the device to be expanded more or less at different intervals along the length of the device, so as to expand outwardly into engagement with the irregularly shaped vessel, such as the aorta. Applicant's device can be positioned with its ring stents displaced from the intersecting artery or from the aneurysm so as to avoid obstruction of blood flow or to avoid the application of excessive stress against the wall of the vessel. This is not disclosed by Clouse.

Indeed, the substitution of ring stents of Lam is not suggested by the references. Clouse describes a cylindrical structure, not one that might vary in breadth along its length, and Clouse utilizes a two piece product, with the outer structural skeleton 30 surrounding the inner expandable tubular member 40. This is no indication that there is the opportunity for flow of blood laterally through the multiple structure of Clouse. Therefore, there is no suggestion that Clouse could be modified to provide the flexible construction or the function provided by applicant.

Dependent claim 2 adds the feature of the tubular sheath extending less than the full length of the longitudinal support rods, leaving a portion of the support rods uncovered for the passage of blood. This is not disclosed by the applied references.

Dependent claim 3 adds the feature of the tubular sheath having a passage formed therethrough between the first and second ends that provides a fluid access between the rods. This is not shown by the applied prior art.

Dependent claim 4 adds the feature of the ring stents being expandable to selected progressively uncoiled positions so that the structural frame can be expanded to different breadths along its length. This is not disclosed by the applied prior art.

Dependent claim 5 adds the limitation of the longitudinal support rods being flexible and able to conform to the shape of the vessel between the ring stents. Again, this is not disclosed by the applied prior art.

Dependent claim 6 specifies that the sheath surrounds the structural frame, and the ring stents engage the structural frame. This is not disclosed in the applied art.

Dependent claim 7 specifies that the ring stents are each arranged in a coil and are expandable for urging the structural frame toward engagement with the interior surface of an irregularly shaped vessel. This is not disclosed by the applied prior art.

New independent claim 8, based on original claim 1, includes among its limitations the feature that the elongated flexible support members are devoid of the sheath at a position along the length of the elongated flexible support members so that blood may pass therethrough. This is not disclosed by the applied prior art.

New independent claim 9 describes the elongated flexible support members supported at intervals by the ring stents. This provides the advantages described above that are not available in the applied art.

Applicant submits that the claims of the application adequately distinguish over the art, and favorable reconsideration of the application is requested:

Respectfully submitted,



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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, postage prepaid, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on

May 13, 2003

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Signature – Mary N. Kilgore